IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Robert Sackstein Art Unit : 1644
Serial No. : 10/042,421 Examiner : Phillip Gambel
Filed : October 18, 2001
Title : HEMATOPOIETIC CELL E-SELECTIN/L-SELECTIN LIGAND POLYPEPTIDES

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
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DECLARATION OF ROBERT SACKSTEIN, M.D., PhD UNDER 37 CFR §1.132

I, Robert Sackstein, M.D., PhD, pursuant to 37 C.F.R. § 1.132, declare the following:

1. My educational and professional experience and qualifications are presented in the attached Curriculum Vitae (Appendix A).

2. I am the named inventor on the above-referenced United States Patent Application, No. 10/042,421.

3. I have reviewed the Office Action dated January 26, 2005 regarding the above-referenced application and understand that the Examiner has rejected the claims as anticipated by Stamenkovic et al. (1991) EMBO Journal 10:343-348 (referred to hereafter as "Stamenkovic"). In particular, it is my understanding that this rejection is based upon the Examiner's assertion that "given the teaching of the structural characterization (e.g. amino acid and encoding nucleic acids) of the CD44 isoforms as well as the hematopoietic source of said CD44 isoforms ..., the prior art appears to read on the claimed polypeptides."

4. Contrary to the Examiner's assertions, the CD44 isoform disclosed by Stamenkovic is not the same as the claimed glycoprotein, referred to as HCELL. While the CD44 peptide backbone of HCELL can be the same as the CD44 protein disclosed by Stamenkovic, HCELL is specialized glycosylated form of CD44 rendering a high affinity ligand for E-selectin or L-selectin and giving it the property of binding to an antibody having the specificity of monoclonal antibody HECA-452. The CD44 isoform disclosed by Stamenkovic does not have this property. Specifically, the CD44 isoform disclosed by Stamenkovic was produced by tranfected COS cells and Namalwa cells. COS cells and Namalwa cells lack the glycosyltransferases necessary to modify CD44 to become a selectin ligand, i.e., the HCELL glycoform. Neither COS nor Namalwa cells express either CD15s nor HECA determinants. Moreover, COS are well-known to lack fucosyltransferase VII which is important for selectin ligand synthesis. Therefore, the CD44 isoform disclosed by Stamenkovic cannot be glycosylated such that it has the properties required by the claims, namely the ability to bind selectins and to be

recognized by a monoclonal antibody recognizing the relevant selectin-binding carbohydrate determinants (sialofucosylations), such as with the specificity of HECA 452.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

DATE: July 22, 2005

Robert Sackstein, M.D., PhD.

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